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EXAMINER	
VRETTAKOS, PETER J	

ART UNIT	PAPER NUMBER
3739	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,768	SCHATZBERGER, SHAIKE	
	Examiner	Art Unit	
	Pete J. Vrettakos	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 27-63* is/are rejected.

7)☒ Claim(s) *26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11-9-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Applicant is requested to insert into the specification all related priority information.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show descriptors (labeled rectangular box (e.g., box should be labeled as an "imager", "controller", etc.)) (instead the figures show only numbers) as described in the specification. Non-compliant elements in the figures are: 150, 140, 230, 190, 310, 336, 360, 544, 542, 644, 642 and 440.

Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If

the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27-42, 47-52 and 55-63 are rejected under 35 U.S.C. 102(e) as being anticipated by Chornenky et al. (6,994,706).

29. An apparatus for delivering a treatment tool (729) to a treatment site within the body of a subject, comprising: a) a guiding element (720) operable to be placed at a reference site at a first distance from said treatment site, said treatment site being in a first direction from said reference site; and b) a positioning tool (722,724) operable to guide a treatment tool (729) to a locus so positioned that a second distance, from said guiding element (720) to said locus, is substantially similar to said first distance, and a second direction, from said guiding element (720) to said locus, is substantially similar

to said first direction from said reference site to said treatment site.

30. The apparatus of claim 29, wherein said positioning tool (722,724) is a mechanical device operable to position said treatment tool (729) at said second distance from said guiding element (720) and in said second direction from said guiding element (720).

31. The apparatus of claim 29, wherein said positioning tool (722,724) is an electromechanical device operable to position said treatment tool (729) at said second distance from said guiding element (720) and in said second direction from said guiding element (720).

32. The apparatus of claim 29, wherein said positioning tool (722,724) is a position-reporting device operable to report distance and direction from said guiding element (720) to said treatment tool (729), thereby providing information enabling a surgeon to position said treatment tool (729) at a said second distance from said guiding element (720) and in said direction from said guiding element (720).

33. The apparatus of claim 29, further comprising a catheter operable to place said guiding element (720) at said reference site.

34. The apparatus of claim 33, wherein said guiding element (720) is integrated with said catheter.

35. The apparatus of claim 1, further comprising a treatment tool (729) operable to ablate tissue.

36. The apparatus of claim 29, wherein said guiding element (720) is a guiding segment (720) having a length in excess of 1 cm.

37. The apparatus of claim 29, wherein said positioning tool (722,724) comprises a template (722,724) having an aperture sized and shaped to permit passage of said treatment tool (729).

38. The apparatus of claim 37, wherein said aperture is sized and shaped to orient said treatment tool (729) in a predetermined direction.

39. The apparatus of claim 38, wherein said predetermined direction is perpendicular to said template (722,724).

40. The apparatus of claim 37, wherein said template (722,724) comprises a plurality of apertures, each aperture sized and shaped to permit passage of a treatment tool (729).

41. The apparatus of claim 37, wherein said guiding element (720) is a guiding segment (720) which is substantially straight and has a length in excess of 1 cm.

42. The apparatus of claim 41, further comprising orienting means for orienting said template (722,724) in an orientation perpendicular to a long axis of said guiding segment (720).

47. The apparatus of claim 37, wherein said guiding element (720) comprises a signal transmitter and said template (722,724) comprises a signal sensor (col. 5:49-54).

48. The apparatus of claim 47, wherein said signal sensor (col. 5:49-54) is operable to report a signal whose strength is a function of an angle of orientation of said template (722,724) with respect to said guiding segment (720).

49. The apparatus of claim 48, wherein said signal sensor (col. 5:49-54) is operable to report a signal whose strength is at a minimum when said template (722,724) is perpendicular to said guiding segment (720).

50. The apparatus of claim 47, further comprising a plurality of sensors (col. 5:49-54) operable to receive a signal generated by said signal transmitter.

51. The apparatus of claim 50, wherein said plurality of sensors (col. 5:49-54) is operable to report substantially equal signal strengths when said template (722,724) is both perpendicular to, and centered with respect to, said guiding element (720).

52. The apparatus of claim 33, wherein said catheter is operable to be flexible, and also operable to be stiff.

55. The apparatus of claim 33, wherein said guiding element (720) comprises a transmitter.

56. The apparatus of claim 55, wherein said guiding element (720) comprises a sensor (col. 5:49-54) operable to detect a signal transmitted by said signal transmitter and reflected from a treatment tool (729).

57. The apparatus of claim 56, further comprising a display system operable to receive information from said sensor (col. 5:49-54).

58. The apparatus of claim 56, further comprising a controller operable to calculate movements required to deliver said treatment tool (729) to said treatment site, based on information provided by said sensor (col. 5:49-54).

59. The apparatus of claim 55, further comprising a treatment tool (729) which comprises a sensor (col. 5:49-54) operable to detect a signal transmitted by said transmitter.

60. The apparatus of claim 33, wherein said guiding element (720) comprises a sensor (col. 5:49-54), and further comprising a treatment tool (729) which comprises a transmitter, said sensor (col. 5:49-54) is operable to detect a signal transmitted by said transmitter.

61. The apparatus of claim 60, further comprising a display system operable to receive information from said sensor (col. 5:49-54).

62. The apparatus of claim 60, further comprising a controller operable to calculate movements required to deliver said treatment tool (729) to said treatment site, based on information provided by said sensor (col. 5:49-54).

63. An apparatus for delivering a treatment tool (729) to a treatment site in the body of a subject, comprising: a) an imaging (ultrasound) device; b) a catheter which comprises a guiding element (720) designed and constructed to be rendered visible by said imaging (ultrasound) system, and to appear distinct from other objects imaged by said imaging (ultrasound) system; and c) a treatment tool (729) which comprises a distal portion designed and constructed to be rendered visible by said imaging (ultrasound) system, and to appear distinct from other objects imaged by said imaging (ultrasound) system.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-25,43-46 and 53-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chornenky et al. (6,994,706).

Although the patent does not anticipate the below methods, the patent's structural equivalence makes obvious the methods.

1. A method for delivering a treatment tool (729) to a treatment site within the body of a subject in need thereof, comprising: a) placing a guiding element (720) at a reference site being at a first distance from said treatment site, said treatment site being in a first direction from said reference site; and b) utilizing a positioning tool (722,724) to guide a treatment tool (729) to a locus so positioned that a second distance, from said guiding element (720) to said locus, is substantially similar to said first distance, and a second direction, from said guiding element (720) to said locus, is substantially similar to said first direction from said reference site to said treatment site; thereby positioning said treatment tool (729) substantially at said treatment site.

2. The method of claim 1, wherein said positioning tool (722,724) is a mechanical device operable to position said treatment tool (729) at said second distance from said guiding element (720) and in said second direction from said guiding element (720).

3. The method of claim 1, wherein said positioning tool (722,724) is an electromechanical device operable to position said treatment tool (729) at said second distance from said guiding element (720) and in said second direction from said guiding element (720).

4. The method of claim 1, wherein said positioning tool (722,724) is a position-reporting device operable to report distance and direction from said guiding element (720) to said treatment tool (729), thereby providing information enabling a surgeon to position said treatment tool (729) at a said second distance from said guiding element (720) and in said direction from said guiding element (720).

5. The method of claim 1, further comprising using a catheter to place said guiding element (720) at said reference site.

6. The method of claim 5, wherein said guiding element (720) is integrated with said catheter.

7. The method of claim 1, wherein said reference site is a selected portion of a natural body conduit. See figure 7.

8. The method of claim 7, wherein said natural body conduit is a urethra. See figure 7.

9. The method of claim 7, wherein said natural body conduit is a blood vessel. Made obvious through disclosure of the urethra.

10. The method of claim 7, wherein said natural body conduit is a bronchial tube. Made obvious through disclosure of the urethra.

11. The method of claim 7, wherein said natural body conduit is an intestine. Made obvious through disclosure of the urethra.

12. The method of claim 7, wherein said natural body conduit is a colon. Made obvious through disclosure of the urethra.

13. A method for treating tissue at a treatment site within the body of a subject, comprising: a) delivering a treatment tool (729) to a treatment site within the body of a subject, by i) placing a guiding element (720) at a reference site at a first distance from said treatment site, said treatment site being in a first direction from said reference site; and ii) utilizing a positioning tool (722,724) to guide a treatment tool (729) to a locus so positioned that a second distance, from said guiding element (720) to said locus, is substantially similar to said first distance, and a second direction, from said guiding element (720) to said locus, is substantially similar to said first direction, thereby positioning said treatment tool (729) substantially at said treatment site; and b) utilizing said treatment tool (729) to treat said tissue at said treatment site.

14. The method of claim 13, further comprising utilizing said treatment tool (729) to ablating prostate tissue. See figure 7.

15. The method of claim 13, wherein said treatment site is a volume of tissue situated less than a selected maximum distance from said guiding element (720) and more than a selected minimum distance from said guiding element (720).

16. The method of claim 15, wherein said guiding element (720) is a guiding segment (720) having a length in excess of 1 cm.

17. The method of claim 1, wherein said positioning tool (722,724) comprises a template (722,724) having an aperture sized and shaped to permit passage of said treatment tool (729). See figure 7.

18. The method of claim 17, wherein said aperture is sized and shaped to orient said treatment tool (729) in a predetermined direction.

19. The method of claim 18, wherein said predetermined direction is perpendicular to said template (722,724). See figure 7.

20. The method of claim 17, wherein said template (722,724) comprises a plurality of

apertures, each aperture sized and shaped to permit passage of a treatment tool (729). See figure 7.

21. The method of claim 17, wherein said guiding element (720) is a guiding segment (720) which is substantially straight and has a length in excess of 1 cm. See figure 7.

22. The method of claim 21, further comprising orienting said template (722,724) to be perpendicular to a long axis of said guiding segment (720). See figure 7.

23. A method for treating Benign Prostate Hyperplasia by ablating prostate tissue proximate to, but not contiguous to, a prostatic urethra, comprising: a) utilizing a catheter (see figure 7) to introduce into a prostatic urethra a substantially straight guiding segment (720) oriented in a first orientation; b) orienting a template (722,724) having a plurality of apertures spaced around a central point, so that said template (722,724) is perpendicular to said first orientation; c) centering said template (722,724) with respect to said guiding segment (720) in such a way that a line, in said first orientation, extending from said guiding segment (720) to said template (722,724), would intersect said template (722,724) at said central point; d) deploying a plurality of treatment tool (729)s through said plurality of apertures; and e) utilizing at least some of said treatment tool (729)s to ablate tissue of said prostate, thereby treating Benign Prostate Hyperplasia by ablating prostate tissue proximate to, but not contiguous to, a prostatic urethra.

24. The method of claim 5, wherein said catheter comprises a plurality of joints lockable at fixed angles. See MPEP § 2144.04 IV B and V C.

25. The method of claim 5, wherein said catheter comprises a plurality of variable joints joining rigid segments, each of said variable joints is operable to report an angle at which segments adjacent thereto are joined. See MPEP § 2144.04 IV B and V C.

27. The method of claim 25, further comprising orienting said plane of said template (722,724) by selecting a template (722,724) position which minimizes a signal, received at a sensor (col. 5:49-54) mounted on said template (722,724), which signal originates at a signal transmitter proximate to said guiding segment (720).

28. The method of claim 25, further comprising centering said template (722,724) with respect to said guiding segment (720) by selecting a template (722,724) position which equalizes strengths of signals received at a plurality of sensor (col. 5:49-54)s monitored on said template (722,724), which signals originate at a signal transmitter proximate to said guiding segment (720).

43. The apparatus of claim 33, wherein said catheter comprises a plurality of joints lockable at fixed angles. See MPEP § 2144.04 IV B and V C.

44. The apparatus of claim 33, wherein said catheter comprises a plurality of variable joints joining rigid segments, each of said variable joints is operable to report an angle at which segments adjacent thereto are joined. See MPEP § 2144.04 IV B and V C.

45. The apparatus of claim 44, further comprising a servomotor (730) operable to orient said template (722,724) perpendicularly to said guiding segment (720). See MPEP § 2144.04 IV B and V C.

46. The apparatus of claim 45, wherein said servomotor (730) is operable to orient said template (722,724) with respect to said catheter at an angle calculated as a function of a sum of said reported angles of said plurality of variable joints. See MPEP § 2144.04 IV B and V C.

53. The apparatus of claim 52, wherein said catheter comprises an inflation lumen, and said catheter is operable to be rendered stiff by introduction of pressurized fluid (711) into said inflation lumen.

54. The apparatus of claim 52, wherein said catheter is operable to be stiffened by insertion of an insertable stiffening element (727).

Allowable Subject Matter

Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The claim reads "orienting a positioning tool (722,724) with respect to said guiding segment (720) by attaching said positioning tool (722,724) to said catheter at **an angle calculated as a function of a sum** of said reported angles of said plurality of variable joints". The method of using a calculated angle as claimed is not found or suggested in the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pete J. Vrettakos whose telephone number is (571)272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Roy D. Gibson/
Primary Examiner, Art Unit 3739

/Pete Vrettakos/
March 30, 2008